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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------------|--------------------|
| 09/664,588 | 09/18/2000 | Jaime Vargas | 032405-003 | 4754 |
| 33109 | 7590 | 09/04/2003 | | |
| CARDICA, INC. 900 SAGINAW DRIVE REDWOOD CITY, CA 94063 | | | EXAMINER DAVIS, DANIEL J | |
| | | | ART UNIT 3731 | PAPER NUMBER 28 |
| | | | DATE MAILED: 09/04/2003 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

| | | |
|------------------------------|----------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/664,588 | VARGAS ET AL. |
| | Examiner D. Jacob Davis | Art Unit 3731 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 38,41-43,45-49,53-60,64-72 and 76-84 is/are rejected.
- 7) Claim(s) 39,40,44,50,51,52 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

Claim 43 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 42. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 38, 42, 43, 46-48, 53-59 are rejected under 35 U.S.C. 102(e) as being anticipated by Bolduc et al. (US 6,193,734). As illustrated in Figures 10-12, Bolduc discloses an anastomosis system comprising a handle, a holder tube/first member 18B, an expander/second member 16B, a trocar 34B, and a plurality of slits/hooks 40B for receiving pull tabs 38B.

Figures 3-5 illustrate another embodiment of the invention comprising a handle, a holder tube 18, and an expander 16.

Regarding claims 46-48, Bolduc's anastomosis system inherently must have a handle that is connected to either the expander or the holder tube or both. The handle may be rotated about an axis (though that does not necessarily mean that the handle is a cylinder that rotates relative to another cylinder). As the handle is rotated, it must rotate both the expander and the holder tube.

Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 45 and 49 are rejected under 35 U.S.C. 103(c) as being unpatentable over Bolduc. Regarding claim 45, Bolduc discloses the system in Figures 3-5 and 10-12 according to claim 38 but is silent regarding the details of the handle. Nevertheless, Figure 16 discloses a handle 88 that would be attached to and move the expander 16, 16B relative to the holder tube 18, 18B. Therefore, it would have been obvious to

one of ordinary skill in the art at the time the invention was made to modify the inventions of figures 3-5 and 10-12 to include the handle 88 as disclosed in figure 16 so that the expander/first member 16,16B and the holder tube/second member 18,18b can be longitudinally moved relative to one another.

Regarding claim 49, the handle (Figure 16) comprises elements 88, 92, 90 and has a cam groove. The cam groove is the lumen of element 92 through which element 64 passes.

Claims 60, 64-72 and 76-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suyker in view of Gifford, III et al. (US 5,695,504). In Figs. 28-30, Suyker discloses a first member 37, a second member 42,44, and a handle (proximal portions of elements 40,44). However, he fails to disclose that the handle may be rotated to move the expander or the holder tube. (Since the two elements move relative to one another, movement of one inherently results in the movement of the other).

Nevertheless, Gifford (Figs. 4-5E) discloses an anastomosis deployment device wherein the rotation of a handle rotates threadedly engaged tubes relative to one another. As one of the tubes is rotated, both move laterally relative to one another resulting in a crimped anastomosis device. The threaded rotational advancement enables greater precision and force during deployment. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Suyker deployment device as taught by Gifford to add threads between the tubes 40 and 37, and between 37 and 44, to advance the device with more precision and force.

With threads added to selectively advance the Suyker device, the handle may be rotated about the axis in order to translate the first and second members relative to one another.

Response to Arguments

Applicants' arguments with respect to claims 38-59 have been considered but are moot in view of the new grounds of rejection.

Applicants' arguments with regard to the rejection of claims 60, 72 and their depending claims over Suyker in view of Gifford are not persuasive. Examiner acknowledges that threads in and of themselves are not required to meet the claim. However, they are required for the Suyker device to meet the claim since relative axial rotation of the members would cause a relative translation.

Allowable Subject Matter

Claims 39, 40, 44, and 50-52 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: the prior art fails to disclose or suggest a trocar that receives the anastomosis device (claim 39), an expander having an annular groove (claim 50) and in combination with all of the other limitations. The prior art fails to disclose or suggest "a handle includes two cam grooves, and the holder tube and expander each have a follower member engages in one of the

cam grooves to move the holder tube and the expander with respect to one another upon activation of a trigger of the handle," (claim 41) and in combination with the other limitations.

The prior art fails to disclose or suggest the, "holder tube having flexible fingers that flex outward to form a proximal flange" and in combination with all of the other limitations (claim 44).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

DJD
August 29, 2003


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700